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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,891	01/05/2004	Holger Puchta	532622003100	2084
<div>7590 12/26/2007 Roberte M. D. Makowski Connolly Bove Lodge &amp; Hutz LLP 1007 North Orange Street P.O. Box 2207 Wilmington, DE 19899</div>			<div>EXAMINER ZHENG, LI</div> <div>ART UNIT 1638</div> <div>PAPER NUMBER</div>	
			<div>MAIL DATE 12/26/2007</div>	<div>DELIVERY MODE PAPER</div>

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/750,891	<b>Applicant(s)</b> PUCHTA ET AL.	
	<b>Examiner</b> Li Zheng	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 5-26, 29-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 27 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 24, 2007 has been entered.

2. Claims 1-30 are pending. Claims 5-30 are withdrawn for being drawn to non-elected inventions. Claims 1-4 are examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 102***

4. The rejection of claims 1-4 and 27-28 under 35 U.S.C. 102(b) as being anticipated by Lyznik et al. is withdrawn due to claim amendment.

5. The rejection of claims 1-4 and 27-28 under 35 U.S.C. 102(e) as being anticipated by Dujon et al. et al. is withdrawn due to claim amendment.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-4 and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dujon et al. (U.S. Patent No. 6,395,959).

Dujon et al. teach that a recombination system comprising a vector comprising from 5' to 3' a LTR sequence, a I-SceI type II restriction enzyme recognition site as a recognition sequence for site-directed induction of DNA double-strand breaks, a Phleomycin selection marker, another LTR sequence and I-SceI type II restriction enzyme recognition site and a second Phleomycin selection marker, as well as a second viral vector expressing I-SceI type II restriction enzyme (Figures 25). The two LTR sequences or Phleomycin selection markers meet the structural limitations for homology sequence A and B of the instant claims.

Dujon et al. do not teach that after recombination the resulting transgenic sequence does not contain any I-SceI site.

However, it would have been obvious for a person with ordinary skill in the art to modify the vector of Dujon et al. by deleting one of the I-SceI site, resulting in the instant invention with a reasonable expectation of success. One would have been motivated to do so given the teaching of Dujon that either one of the I-SceI sites alone is sufficient to produce the same recombinant transgenic sequence (Figure 25B part (1) and (2)).

Applicants argue that instant claim 1 recites that the recognition sequence for site-directed induction of double-stranded breaks is found between homologous sequences A and B (response, page 10, last paragraph). However, as clearly shown in Figure 25B of Dujon, the left I-SceI site is between two homologous LTR regions (open boxes) whereas the right I-SceI site is between two homologous PhleoLacZ regions (filled boxes).

Applicants further argue that instant claim 1 recites that the recognition sites are deleted after recombination between two homologous regions (response, page 10, last paragraph). However, as clearly shown in Figure 25B of Dujon, the left I-SceI site is deleted after the homologous recombination between two homologous LTR regions whereas the right I-SceI site is deleted after homologous recombination between two homologous PhleoLacZ regions. The homologous sequence may not be the full length of LTR but rather either side of the LTR divided by the I-SCE I site.

***Summary***

Claims 1-4 and 27-28 are rejected.

No claim is allowed.

***Summary***

No claim is allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ASHWIN D. MEHTA, PH.D.  
PRIMARY EXAMINER

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